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10/687,636

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Patrick Rambaud

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EXAMINER

WHALEY, PABLO S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/687,636 | Applicant(s) RAMBAUD, PATRICK | |
| | Examiner PABLO WHALEY | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7, 11-18, 20-22, 25 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 11-14, and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15-18, 20, 21, 25 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1, 2, 3, 6, 7, 11-18, 20-22, 25, and 30-34 are pending.

Claims 1, 2, 15-18, 20-21, 25, and 30-34 are rejected.

Claims 4-5, 8-10, 19, 23-24, and 26-29 are cancelled.

Claims 3, 6, 7, 11-14, and 22 are withdrawn.

Withdrawn Rejections

The rejection of claims 1, 15-18, 20, 25, and 30-33 are rejected under 35 U.S.C. 102 (a) as being anticipated by Lefesvre is withdrawn in view of applicant's amendments, filed 09/05/2008.

Claim Rejections - 35 USC § 101

Claims 1, 2, 15-18, 20-21, 25, and 30-34 have been fully considered with regards to 35 U.S.C. 101 and are directed to statutory subject matter, as the claims recite physical transformations of matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 15-18, 20, 25, 30-33, and 35 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5).

This new ground of rejection is necessitated by applicant's amendments, filed 09/05/2008.

Lefesvre teaches batch management system for managing lymphocytes (i.e. immunocompetent cells) or monocytes for differed uses [Abstract]. In particular, Lefesvre teaches the collection of information obtained by the processing of blood that inherently yields information indicative of the status of health of the patient [p. 1 and Fig. 1], which shows a status characterization step of collecting information since the claims do not require active limitations for characterizing data beyond the collection of information and since process by which the data was obtained has no restrictive effect on the instant method. Lefesvre teaches collecting and preserving cells, and means for storing lymphocyte data from multiple batches [p.3]. Lefesvre teaches personal libraries obtained from successively taken batches for preserving immunizing information taken from immuno-qualified cells, and processing of information that includes cellular identification, immunity related information, and gene therapy protocol information [p.2, ¶8, p.2, ¶ 12], and means for storing and managing this information [Fig. 1, p.3]. Lefesvre teaches and localization of one or more stored batches of immuno-qualified cells, followed by transferring batch information to a cellular processing center (i.e. expert system) [p.2, ¶ 2, p.4, ¶ 4]. Lefesvre teaches protocols for performing an identification comprising a new cellular identification, consulting a cell management database system[p.3, ¶1-¶3], receiving requests for subject identity data [p.3, last ¶], and processing of the database based on patient specific requests [p.4, last ¶, p.4]. Lefesvre teaches extracting selected cells from a personal library according to deferred use protocols in view re-using lymphocytes in the patient [p.4, ¶ 2, and p.4, ¶7 onwards]. Lefesvre teaches checking operations of quality (i.e. checking for annihilation of antibodies) [p.4, ¶ 2]. Lefesvre teach gene therapy protocols [p.2, ¶ 12], and a plurality of sites of cryogenic storage designed to receive the batches of immuno-qualified cells [p.3, ¶ 2]. Lefesvre teaches taking blood from a patient, a treatment of taken blood and a separation of the lymphocytes and/or

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monocytes, a cellular identification, a fractionation to carry out a whole of batches of lymphocytes and/or monocytes, a preparation of the lymphocytes and/or monocytes, including dehydration, grouping and setting in cryogenic storage of N batches of lymphocytes and/or monocytes [p.3, ¶ 9].

Lefesvre does not teach specifically teach performing an identification of batches of cells by consulting a cell management database, as in claim 1. However, this limitation would have been obvious to one of ordinary skill in the art since Lefesvre teaches cell management system that determines the localization and cellular identification of specific batches for processing [p.4, ¶1] and provides a database that can be queried by a user to obtain information [p.3, last ¶]. The motivation would have been to improve system productivity using the latest computer-based methods for identifying batches of cells, as suggested by Lefesvre [p.3, ¶10 onwards].

Claims 1, 2, 15-18, 20, 21, 25, and 30-35 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5), in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

Lefesvre teaches method and system for management of batches of immuno-qualified cells for differed uses [Abstract], as set forth above.

Lefesvre does not teach bioelectronic information collected from blood, as in claims 2, 21, and 34.

Cha teaches a routine method for obtaining bioelectronic information by processing previously collected patient blood samples. The information includes resistance (i.e. resistivity) and reactance data [Abstract, Fig. 1, Section 3], as in claims 2, 21, and 34.

It would have been obvious to some one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system taught of Lefesvre by collecting bioelectronic information from blood, as in claims 2, 21, and 34, since Cha teaches routine methods for obtaining such

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information from blood, as set forth above. The motivation would have been to improve the management system by including more accurate blood information measurements, suggested by Cha et al. [p.136, ¶ 3 and 4].

Response to Arguments

Applicant's arguments, filed 09/05/2008, have been fully considered.

Applicant's argument that Lefesvre does not disclose performing an identification of the batches of cells by consulting said cell management database, and receiving from said cell management database said subject's identity data, are persuasive. However, a new ground of rejection has been applied in view of applicant's amendments filed 09/05/2008.

In response to applicant's argument that Lefesvre does not disclose a status-characterization step collecting the subject's health status of health and/or psychological status from the subject's samples, where the said status-characterizing information yields a subject status characterization indicating the subject's health status and/or the psychological status of said subject, Lefesvre teaches the collection of information obtained by the processing of blood that inherently yields information indicative of the status of health of the patient [p. 1 and Fig. 1], which shows a status characterization step of collecting information since the claims do not require active limitations for characterizing data beyond the collection of information and since process by which the data was obtained has no restrictive effect on the instant method.

In response to applicant's argument that Lefesvre does not teach or suggest determining the subject's identity data, Lefesvre determines information that includes cellular identification, immunity related information, and therapeutic protocol information [p.2, ¶8, p.2, ¶ 12].

In response to applicant's argument that Lefesvre does not teach extracting selected immunocompetent cells, Lefesvre teaches extracting selected cells from a personal library according to deferred use protocols in view re-using lymphocytes in the patient [p.4, ¶ 2, and p.4, ¶7 onwards].

Obviousness Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,415,201 (Issued Jul. 2, 2002) in view of Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5). The instant claims and those of US 6,415,201 both are directed to methods and system for managing batches of cells collected from subjects for deferred use, with minor variations. US 6,415,201 shows the collection of batches of components of the haemopoietic system, and are therefore generic to instant claims. US 6,415,201 does not show the collection of immunity information or health status information for immunocompetent cells. Lefesvre et al. shows the collection and processing of status characterizing information (i.e. blood) for immunocompetent cells, and shows processing blood to obtain information related to patient health. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to practice the system for managing batches of cells as taught by US 6,415,201 to collect immunity information for

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managing immunocompetent cell batches in view of Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5), since components of the haemopoietic system include immunocompetent cells.

Response to Arguments

Applicant's arguments, filed 09/05/2008, have not addressed non-statutory double patenting rejection. Therefore this rejection is maintained for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631